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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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STERNE, KESSLER, GOLDSTEIN & FOX PLLC
1100 NEW YORK AVENUE, N.W.
WASHINGTON, DC 20005

EXAMINER	
STRZELECKA, TERESA E	

ART UNIT	PAPER NUMBER
1637	

DATE MAILED: 10/16/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/719,978	BUDAHAZI ET AL.	
	Examiner	Art Unit	
	Teresa E. Strzelecka	1637	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *31 July 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-34* is/are pending in the application.

4a) Of the above claim(s) *1-20* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *21-34* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *23 April 2004* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *4/23/04;3/17/05*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Applicant's election with traverse of Group II (claims 21-34) in the reply filed on July 31, 2006 is acknowledged. The traversal is on the ground(s) that searching both inventions together would not be burdensome, since searching for the DNA product of Group II "would lead the examiner to references that disclose the process of purifying the plasmid DNA, as recited in claims 1-20." This is not found persuasive because claims of group II are drawn to the plasmid DNA product, which can be obtained by myriad different purification methods, such as CsCl purification, gel purification, HPLC purification, purification on different types of ion exchange columns, etc. Therefore, for example, search for claim 1, which is drawn to any plasmid DNA, would most definitely not lead to a method of Group I without an additional search, creating a search burden.

The requirement is still deemed proper and is therefore made FINAL.

2. Claims 1-20 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on July 31, 2006.

3. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Information Disclosure Statement

4. The information disclosure statements (IDSs) submitted on April 23, 2004 and March 17, 2005 are in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statements are being considered by the examiner.

Claim Rejections - 35 USC § 112

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claims 22-26 and 30-36 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

A) Claim 22 is indefinite over the recitation of "about 95% or greater by weight". It is not clear what is the lower limit of this range. Applicants did not define what range of values corresponds to the term "about", i.e., what "about 95%" means. Is it 95% $\pm$ 10%, or 20%, or 50%? Therefore, "greater than about 95%" does not delineate a clear lower limit to the range.

B) Claim 23 is indefinite over the recitation of "less than about 5%". The phrase "less than" typically indicates a maximum point. The phrase "less than" however, is contraverted by the term about which implies that values above and below 5% are permitted. Further, the extent of variance permitted by about is unclear in this context, since Applicants did not define the range of values which correspond to the term "about". Therefore, it is also unclear if about 5% simply includes 4% or if it also includes 1-3% as well.

C) Claim 24 is indefinite over the recitation of "less than about 0.002 μg". The phrase "less than" typically indicates a maximum point. The phrase "less than" however, is contraverted by the term about which implies that values above and below 0.002 μg are permitted. Further, the extent

of variance permitted by about is unclear in this context, since Applicants did not define the range of values which correspond to the term "about". Therefore, it is also unclear if about 0.002 μg simply includes 0.001 μg or if it also includes any value between 0 and 0.001 μg as well.

D) Claim 25 is indefinite over the recitation of "less than about 0.001 μg". The phrase "less than" typically indicates a maximum point. The phrase "less than" however, is contraverted by the term about which implies that values above and below 0.001 μg are permitted. Further, the extent of variance permitted by about is unclear in this context, since Applicants did not define the range of values which correspond to the term "about". Therefore, it is also unclear if about 0.001 μg simply includes 0.0005 μg or if it also includes any value between 0 and 0.001 μg as well.

E) Claim 26 is indefinite over the recitation of "less than about 0.01EU/μg". The phrase "less than" typically indicates a maximum point. The phrase "less than" however, is contraverted by the term about which implies that values above and below 0.01 EU/μg are permitted. Further, the extent of variance permitted by about is unclear in this context, since Applicants did not define the range of values which correspond to the term "about". Therefore, it is also unclear if about 0.01 EU/μg simply includes 0.005 EU/μg or if it also includes any value between 0 and 0.01 EU/μg as well.

F) Claims 30-34 are indefinite in claim 30. Claim 30 is indefinite over the recitation of "less than about 5%", less than about 0.002 μg", "less than about 0.001 μg" and "less than about 0.01 EU/μg". The phrase "less than" typically indicates a maximum point. The phrase "less than" however, is contraverted by the term about which implies that values above and below 5% are permitted. Further, the extent of variance permitted by about is unclear in this context, since Applicants did not define the range of values which correspond to the term "about". Therefore, it is

also unclear if about 5% simply includes 4% or if it also includes 1-3% as well. The phrase "less than" however, is contraverted by the term about which implies that values above and below 0.002 μg are permitted. Further, the extent of variance permitted by about is unclear in this context, since Applicants did not define the range of values which correspond to the term "about". Therefore, it is also unclear if about 0.002 μg simply includes 0.001 μg or if it also includes any value between 0 and 0.001 μg as well. The phrase "less than" however, is contraverted by the term about which implies that values above and below 0.001 μg are permitted. Further, the extent of variance permitted by about is unclear in this context, since Applicants did not define the range of values which correspond to the term "about". Therefore, it is also unclear if about 0.001 μg simply includes 0.0005 μg or if it also includes any value between 0 and 0.001 μg as well. The phrase "less than" however, is contraverted by the term about which implies that values above and below 0.01 EU/μg are permitted. Further, the extent of variance permitted by about is unclear in this context, since Applicants did not define the range of values which correspond to the term "about". Therefore, it is also unclear if about 0.01 EU/μg simply includes 0.005 EU/μg or if it also includes any value between 0 and 0.01 EU/μg as well.

Claim Interpretation

7. Applicants did not define the term "about X units", therefore any value below or above a given number X is considered to anticipate this term.

8. Claim is a product-by-process claim. Therefore, according to MPEP 2113 (see below), only the structural properties of the product will be considered when comparing the claims with prior art.

MPEP 2113 Product-by-Process Claims

PRODUCT-BY-PROCESS CLAIMS ARE NOT LIMITED TO THE

MANIPULATIONS OF THE RECITED STEPS, ONLY THE STRUCTURE IMPLIED BY THE STEPS.

"[E]ven though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process." In re Thorpe, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985) (citations omitted) (Claim was directed to a novolac color developer. The process of making the developer was allowed. The difference between the inventive process and the prior art was the addition of metal oxide and carboxylic acid as separate ingredients instead of adding the more expensive pre-reacted metal carboxylate. The product-by-process claim was rejected because the end product, in both the prior art and the allowed process, ends up containing metal carboxylate. The fact that the metal carboxylate is not directly added, but is instead produced in-situ does not change the end product.).

Claim Rejections - 35 USC § 102

9. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

10. Claims 21-34 are rejected under 35 U.S.C. 102(b) as being anticipated by Nochumson et al. (US 2001/0034435 A1; cited in the IDS).

Regarding claims 21 and 27-29, Nochumson et al. teach plasmid DNA and pharmaceutical preparation (page 8, [0099]; claims 8, 11, 19, 31).

Regarding claim 22, Nochumson et al. teach plasmid DNA preparation with 95% plasmid DNA (page 8, [0099]).

Regarding claim 23, Nochumson et al. teach plasmid DNA preparation with less than 5% RNA (page 8, [0099]).

Regarding claim 24, Nochumson et al. teach plasmid DNA preparation with 0.05% of host DNA (page 8, [0099]). Claimed 0.002 μg of host DNA/μg of DNA product is equivalent to 0.2 % of host DNA, therefore Nochumson et al. anticipate this limitation.

Regarding claim 25, Nochumson et al. teach plasmid DNA preparation with less than 0.06% of protein (page 8, [0099]). Claimed 0.001 μg of protein/μg of DNA product is equivalent to 0.1 % of protein, therefore Nochumson et al. anticipate this limitation.

Regarding claim 26, Nochumson et al. teach plasmid DNA preparation with less than 0.2EU/mg of endotoxin, which equals less than 0.0002 EU/μg (page 8, [0099]), anticipating the values of less than about 0.01 EU/μg.

Regarding claims 30-34, Nochumson et al. teach plasmid DNA preparation with 95% plasmid DNA and less than 5% RNA (page 8, [0099]). Nochumson et al. teach plasmid DNA preparation with 0.05% of host DNA (page 8, [0099]). Claimed 0.002 μg of host DNA/μg of DNA product is equivalent to 0.2 % of host DNA, therefore Nochumson et al. anticipate this limitation. Nochumson et al. teach plasmid DNA preparation with less than 0.06% of protein (page 8, [0099]). Claimed 0.001 μg of protein/μg of DNA product is equivalent to 0.1 % of protein, therefore Nochumson et al. anticipate this limitation. Nochumson et al. teach plasmid DNA preparation with less than 0.2EU/mg of endotoxin, which equals less than 0.0002 EU/μg (page 8, [0099]), anticipating the values of less than about 0.01 EU/μg. They teach pharmaceutical preparations (claims 8, 11, 19, 31).

11. No claims are allowed.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Teresa E. Strzelecka whose telephone number is (571) 272-0789. The examiner can normally be reached on M-F (8:30-5:30).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on (571) 272-0782. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Teresa E Strzelecka
Primary Examiner
Art Unit 1637

Teresa Strzelecka
10/10/06